

#04-7984

P.C. 8400128

From: Rivier Scientific Consulting <info@rivier-consulting.com>
To: <wvogl@samhsa.gov>
Date: 7/11/04 6:18PM
Subject: docket # 04-7984

Dear Sir,

As Swiss forensic toxicologist I would like to take the opportunity given to the public to comment on the proposed revision to the federal drug free workplace guidelines that include now alternative testing.

1. The new guidelines require oral fluid collection by spitting in a bottle. This sound quite unpractical when the tested individual is not willing to collaborate. It might become very unsanitary and rather dangerous for the collecting responsible person. In order to overcome all these unpleasant difficulties, I would advise the use of an FDA-cleared collection device should be required.
2. For Cannabis detection, it is required the collect both urine and oral fluid when this latter is planned to be used first. Environmental contamination of urine with Cannabis is known when smoked, and this is why THCA is targeted as analyte of choice. For oral fluid, THC is much better than THCA for both sensitivity and exposure time. THCA is so low in oral fluid that detection time would be very small, even if it might be a good marker for Cannabis consumption as it is for head hair. Environmental contamination seems to me much more a serious problem for head hair rather than for oral fluid. Further, the Cannabis metabolite cut-off for hair and oral fluid is extremely low and require MS/MS instrumentation to be used for confirmation. This would be an extremely expensive routine to maintain and only a few certified laboratories would be able to cope with the corresponding requirements. In view of the many potential positive results, these few laboratories might get into a nightmare ! I would like to advise to look at any of the newest results on passive exposure and oral fluid as well as balancing the interests between THC versus THCA targeted detection before setting a hard to modify pattern for oral fluid cannabis detection. I would like to suggest to screen on THC only and detect both analytes when confirming, this on using oral fluid only. Urine sample analyses would just add confusion on the other results, because of the large differences in THC and metabolites excretion pattern between these two biological matrices.
3. The proposed guidelines do not allow use of oral fluid testing for follow-up and return to duty testing because of its short detection time. Head hair testing is also not ideal because you need repetitive intake of weeks to impregnate hair. When correctly tuned, oral fluid detection time fits very well with plasma time curves. As far as detection rates, oral testing looks rather identical as urine testing (see Cone et al. JAT 26 (2002) 541-6) and oral fluid is much easier to collect when properly done (see above) with less embarrassments for the tested person. I would advocate the use of oral fluid testing be permitted also for follow-up and return to duty testing together with recommendation concerning the time intervals for the necessary repetitive collections of samples.
4. The new guidelines request reporting quantitative determinations to

MRO when positive findings are obtained. It means that uncertainties have to be experimentally set before hand for all analytes using every kind of instrumental settings, with "between all laboratories discrepancies" included within these calculations - not only reference laboratories. This is requested by the ISO 17025 regulations and the SAMHSA guidelines cannot make less than these international quality assurance mandatory requirements. Even if this is highly advisable, it might be difficult to apply these values in practice on a short notice, except if continuous proficiency testings on close to real samples are conducted on a regular basis. The consequence of it might be that the cut-off limit should be extended to more than the requested 50% of its original value. Consequently, I would advise to start the process for the determinations of uncertainty without delay.

Hoping of being of any help in revolving these critical issues, I remain at your disposal for any more detailed comment if desired.

Yours, sincerely

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